UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,845	10/23/2001	Shlomo Ben-Haim	298858-00056	1690

83380 7590 05/12/2011

William H. Dippert
Eckert Seamans Cherin & Mellott, LLC
U.S. Steel Tower
600 Grant Street, 44th Floor
Pittsburgh, PA 15219

EXAMINER	
OROPEZA, FRANCES P	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
05/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

Office Action Summary	Application No.	Applicant(s)	
	10/039,845	BEN-HAIM ET AL.	
	Examiner	Art Unit	
	FRANCES OROPEZA	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/7/11 (Response)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,10-21,23,25 and 28-42* is/are pending in the application.

4a) Of the above claim(s) *41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,10-21,23,25 and 28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/14/10, 10/28/10, 10/31/10, 11/4/10, 1/4/11, 11/11/11, 2/1/11, 2/9/11, 2/10/11, 2/22/11, 2/27/11
.

OFFICE ACTION

Response

1. Applicant's response filed 2/7/11 has been fully considered. The specific argument will be discussed in detail below.

Election/ Restriction

2. Applicant's argument filed 2/7/11 relating to the prosecuting claims 29-40 are convincing, hence the claims being prosecuted in this application are claims 5, 10-21, 23, 25, and 28-40.

The examiner has reviewed the restriction requirement and maintains claims 41-42, submitted 5/4/10 are directed to an invention that is independent or distinct from the invention originally claimed because the invention being prosecuted applies two non-excitatory stimulus to the heart and the invention of claims 41 and 42 applies one excitatory stimuli and one non-excitatory stimuli.

Claim Rejection - 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 5, 10-21, 23, 25 and 28-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Examiner

is unable to find the limitation of biomechanical effects (claim 5) and 100 to 500 consecutive heart beats (claim 35). New matter may not be introduced at this point in the prosecution. Appropriate correction is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 is not clear as a "first non-excitatory stimulus" includes "only non-excitatory stimuli. Clarification is needed

Claim Rejection 35 U.S.C. 102

7. Claims 5, 13-17, 19-21, 23, 25, 30-32, 34 and 36-40 are rejected under 35 U.S.C 102(b) as being anticipated by U.S. Patent No. 4,554,922 to Prystowsky et al, hereafter Prystowsky.

As to claim 5, Prystowsky discloses a heart control apparatus (50), comprising:

- circuitry for generating a non-excitatory stimulus, configured to generate at least two different stimuli; and

> **Prystowsky discloses** a pacing system (50) comprising a programmable stimulator (60), the circuitry for generating non-excitatory stimulus (abstract, lines 2-6), configured to generate at least two different stimuli (column 1, lines 54-60; column 2, lines 2-11).

- a plurality of stimulus application devices for applying to a heart or to a portion thereof said non-excitatory stimuli;

Prystowsky discloses multiple electrodes (62, 64, 66, 68, 70, 72), read as a plurality of stimulation application devices,

- wherein a first one of said devices delivers a first non-excitatory stimulus to a first portion of the heart, using first delivery parameters, and
- wherein a second one of said devices delivers a second non-excitatory stimulus to a second portion of the heart using second delivery parameters,
- wherein said first delivery parameters are different from said second delivery parameters and thereby cause different biomechanical effects on tissue to which they are applied.

Prystowsky discloses multiple devices/ electrodes provide non-excitatory stimulus, the delivery parameters of at least voltage varying between the first stimulus at a first portion of the heart, and the second stimulus at a second portion of the heart (column 1, lines 54-62). The biomechanical effects of the first stimulus and the second stimulus are accepted to be different as the cardiac tissue at two separate locations is different and the voltage supplied to the tissue at each of the two locations is different, hence the biomechanical effects are different.

As to claim 13, **Prystowsky discloses** simultaneous application of said first and second stimuli (column 1, lines 63-68).

As to claim 14, Prystowsky discloses a heart control apparatus that controls the number and frequency of the electrical pulses, hence controlling the heart for a few beats, every certain period of time (column 5, lines 19-24, 48-60 and1-8).

As to claim 15, Prystowsky discloses the first effect is a modification of contractility without a change in heart rate and without affecting a regular activation of the heart. The contractility is modified as a stimulus delivered after the refractory period may not be propagated (column 1, lines 28-31). The conditioning electrical stimuli are provided to the cardiac tissue so the heart rate is maintained at a desired level and regular activation of the heart is supported (column 5, lines 48-60; column 6, lines 29-41column 4, lines 55-58).

As to claim 16, Prystowsky discloses the first effect and said second effect are configured for non-arrhythmic tissue, as the stimulation is provided to inhibit arrhythmias and prevent their occurrence (column 2, lines 12-13).

As to claim 17, Prystowsky discloses the circuitry is configured for a non-arrhythmic heart , as the stimulation is provided to inhibit arrhythmias and prevent their occurrence (column 2, lines 12-13).

As to claim 19, Prystowsky discloses the first effect is a decrease in contractility. As shown in figures 2-7, the application of the conditioning electrical stimuli is varied in both the atria and the ventricle so optimal stimulation can be applied to prevent arrhythmic heartbeats and the resulting decrease in contractility (column 6, lines 29-45).

As to claim 20, Prystowsky discloses the first effect is an increase in contractility. As shown in figures 2-7, the application of the conditioning electrical stimuli is varied in both the atria and the

ventricle so optimal stimulation can be applied to maintain rhythmic heartbeats and the resulting increase in contractility (column 6, lines 29-45).

As to claim 21, Prystowsky discloses the first non-excitatory stimulus is configured to have the first effect on non-arrhythmic tissue, as the stimulation is provided to inhibit arrhythmias and prevent their occurrence (column 2, lines 12-13).

As to claim 23, Prystowsky discloses the first stimulus and said second stimulus include only non-excitatory stimuli (abstract, lines 2-6).

As to claim 25, Prystowsky discloses the first non-excitatory stimulus is applied only if said circuitry determines that said heart is not in an abnormal activation. The sensor determines the heart is in rhythmic heartbeats, and not arrhythmic heartbeats (column 6, lines 1-2), and if there is arrhythmic heartbeats the first excitatory stimulus is modified, and not applied, the modification based on the site of the arrhythmia development and the type of arrhythmia (column 5, lines 48-60).

As to claim 30, Prystowsky discloses the circuitry is also configured to separately pace two chambers of the heart, the atria and the ventricle (column 4, lines 55-58; column 5, line 61 – column 6, line 11).

As to claim 31, Prystowsky discloses the circuitry is also configured to provide an excitatory stimulus to at least one of said delivery devices, as all the electrodes can be used for excitatory and non-excitatory (conditioning electrical stimulus) (column 5, line 61 - column 6, line 8; column 6, lines 16-24).

As to claim 32, Prystowsky discloses the circuitry is configured to generate said two stimuli within a same heart beat, as multiple stimuli can be delivered in the refractory period following a cardiac beat (column 1, lines 54-57).

As to claim 34, Prystowsky discloses at least one sensor, a heart beat sensor, and wherein said circuitry is configured to modify said applying in response to an input from the sensor, where the heart beat sensor senses rhythmic and arrhythmic heart beats, and where the site of the arrhythmia development and the type of arrhythmia impact the applying in terms of the stimulation frequency, pulse width, and current (column 5, lines 48-60; column 6, lines 1-2).

As to claim 36, Prystowsky discloses the first delivery parameters are selected so that a direct effect of said first stimulus on cardiac tissue to which it is applied includes an increase in cellular level contractility. As shown in figures 2-7, the application of the conditioning electrical stimuli is varied in both the atria and the ventricle so optimal stimulation can be applied to maintain rhythmic heartbeats and the resulting increase in contractility (column 6, lines 29-45).

As to claim 37, Prystowsky discloses the first delivery parameters and said second delivery parameters are different in a duration of stimulus application (column 5, lines 50-52).

As to claim 38, Prystowsky discloses the first delivery parameters and said second delivery parameters are different in a timing of stimulus application (column 1, lines 54-57; column 2, lines 3-5).

As to claim 39, Prystowsky discloses the first delivery parameters and said second delivery parameters are different in an amplitude of stimulus application (column 1, lines 54-60; column 7, lines 3-6).

As to claim 40, Prystowsky discloses the first delivery parameters and said second delivery parameters are reflect in different waveforms, as the amplitude of the two parameters is different application (column 1, lines 54-60; column 7, lines 3-6).

8. Claims 5, 10-12, 28, 29 and 35 are rejected under 35 U.S.C 102(e) as being anticipated by U.S. Patent No. 5,562,708 to Combs et al, hereafter Combs.

As to claim 5, Combs discloses a heart control apparatus (1), comprising:

- circuitry for generating a non-excitatory stimulus, configured to generate at least two different stimuli; and

Combs discloses a pacing system (1) comprising circuitry for generating non-excitatory stimulus, timing and control logic (500), microprocessor (502), and memory (504, 506) configured to generate at least two different stimuli (column 2, lines 3-7, 25-28; column 2, lines 3-7; column 6, lines 28-42).

- a plurality of stimulus application devices for applying to a heart or to a portion thereof said non-excitatory stimuli;

Combs discloses multiple electrodes (112, 115), read as a plurality of stimulation application devices, each electrode supplied with its own conductor (column 5, lines 45-66),

- wherein a first one of said devices delivers a first non-excitatory stimulus to a first portion of the heart, using first delivery parameters, and
- wherein a second one of said devices delivers a second non-excitatory stimulus to a second portion of the heart using second delivery parameters,
- wherein said first delivery parameters are different from said second delivery parameters and thereby cause different biomechanical effects on tissue to which they are applied.

Combs discloses multiple devices/ electrodes providing non-excitatory stimulus, the delivery parameters varying between the first stimulus at a first portion of the heart (112), and the second stimulus at a second portion of the heart (115) (column 2, lines 53-67; column 5, lines 30-41). The biomechanical effects of the first stimulus and the second stimulus are accepted to be different as the cardiac tissue at two separate locations is different and the polarity, pulse interval , amplitude and frequency of the pulse supplied to the tissue at each of the two locations is different, hence the biomechanical effects are different.

As to claim 10, Combs discloses the first portion of the heart is the left ventricle and the second portion of the heart is the right ventricle, as the invention may be applied to the two atria or the two ventricles (column 4, lines 11-19).

As to claim 11, Combs discloses the contraction of the left ventricle and the contraction of the right ventricle is modified. While the stimulation is non-excitatory for much of the cardiac

tissue, synchrony between the tissue at the stimulation site in the right ventricle and at the stimulation site in the left ventricle bring greater synchrony over time to the stimulation sites (column 4, line 59 – column 5, lines 17).

As to claim 12, Combs discloses simultaneously controlling both ventricles, one control increasing the flow from one ventricle while the other control decreases the flow from the other ventricle. With stimulation, contraction of the left ventricle and the contraction of the right ventricle is modified. While the stimulation is non-excitatory for much of the cardiac tissue, synchrony between the tissue at the stimulation site in the right ventricle and at the stimulation site in the left ventricle bring greater synchrony over time to the stimulation sites (column 4, line 59 – column 5, lines 17). This synchrony at the right ventricular site and the left ventricular site will enable synchronization of the right and left ventricles (column 4, line 59 – column 5, lines 17). As the two ventricles are synchronized, the flow from the larger ventricle, the left ventricle, is increased while the flow from the smaller ventricle, the right ventricle, is decreased.

As to claim 28, Combs discloses the apparatus is configured to control a synchronization of the contractions of the left and right left ventricles. While the stimulation is non-excitatory for much of the cardiac tissue, synchrony between the tissue at the stimulation site in the right ventricle and at the stimulation site in the left ventricle bring greater synchrony over time to the stimulation sites. This synchrony at the right ventricular site and the left ventricular site will enable synchronization of the right and left ventricles (column 4, line 59 – column 5, lines 17).

As to claim 29, Combs discloses a heart control apparatus (1), comprising:

- circuitry for generating a non-excitatory stimulus: timing and control logic (500), microprocessor (502), and memory (504, 506) (column 2, lines 3-7, 25-28; column 2, lines 3-7; column 6, lines 28-42).

- a sensor which measures a physiological activity, the rate responsive sensor accepted to be monitoring motion or respiration as is typical in the rate responsive cardiac stimulation art (column4, lines 49-55).

- stimulus application devices for applying to a heart or to a portion thereof said non-excitatory stimuli according to the electrification pattern which results in a desired activation profile ;

Combs discloses multiple electrodes (112, 115), read as a plurality of stimulation application devices, each electrode supplied with its own conductor to provided stimulation based on the programmed parameters (column 5, lines 45-66),

- wherein said circuitry for generating a non-excitatory stimulus generates a stimulus which is unable to generate a propagating action potential (column 2, lines 3-7, 25-28; column 2, lines 3-7), configured for

- a first non-excitatory stimulus to a first portion of the heart, the first non-excitatory stimulus having a first effect on the biomechanical behavior of the first portion of the heart, and
- a second non-excitatory stimulus to a second portion of the heart, the second stimulus having a second effect on the biomechanical behavior of the second portion of the heart, the first and the

second effects being different from each other,

- wherein the desired activation profile defines a synchronization of the contractions of the left and the right ventricles.

Combs discloses multiple devices/ electrodes providing excitatory (408, 410, 412) and non-excitatory (112) stimulus, to a first portion of the heart and second portion of the heart respectively (column 2, lines 53-67; column 5, lines 30-41; column 6, lines 10-21). The biomechanical effects of the first stimulus and the second stimulus are accepted to be different as the cardiac tissue at two separate locations is stimulated with a different amount of energy, such that the potential to excitation cardiac tissue is different. With this excitatory and non-excitatory stimulation, contraction of the left ventricle and the contraction of the right ventricle is modified. While the stimulation from the first stimulus is non-excitatory for much of the cardiac tissue, synchrony between the tissue at the first stimulation site brings greater synchrony over time to the first stimulation site (column 4, line 59 – column 5, lines 17). Excitatory stimulation unifies the cardiac tissue at the second stimulation site if timed appropriately. The first portion of the heart is read as the right ventricle and the second portion of the heart is read as the left ventricle, as the invention may be applied to the two atria or the two ventricles (column 4, lines 11-19). The synchrony at the first and second stimulation sites enables synchronization of the right and left ventricles (column 4, line 59 – column 5, lines 17).

As to claim 35, Combs discloses the circuitry is configured to provide the applying for at least 100 out of 5000 consecutive heartbeats. Combs discloses delivering extended series of pacing pulses (e.g.20-100), read to be 100 pulses, hence a successful application of 100 pulses

and then a period of none arrhythmic activity would be applying the stimulation for at least 100 out of 5000 consecutive heartbeats. Lacking criticality 5000 heartbeats is accept to be a design choice.

Claim Rejection 35 U.S.C. 103

9. Claims 5 and 18 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent No. 5,411,531 to Hill et al., hereafter Hill, in view of U.S. Patent No. 5,243,980 to Mehra et al, hereafter Mehra.

Hill discloses a fat pad stimulator (200), comprising:

- circuitry for generating a non-excitatory stimulus to the AV fat pad to control the A-V interval, enabling feedback with a heart rate sensor to increase the cardiac output (column 2, lines 31-45; column 12, lines 4-9) , the circuitry comprising: microprocessor (324), pacer and timing control (312), burst generator (322), and sensor (328) (figure 3),

- electrodes (610, 616), read a plurality of stimulus application devices, for applying to a heart or to a portion thereof the non-excitatory stimuli (column 3, lines 32-41);

As discussed in the previous paragraph of this action, Hill discloses the claimed invention accept:

- the circuitry configured to generate at least two different stimuli,

- wherein a first one of said devices delivers a first non-excitatory stimulus to a first portion of the heart, using first delivery parameters, and

- wherein a second one of said devices delivers a second non-excitatory stimulus to a second

portion of the heart using second delivery parameters,

- wherein said first delivery parameters are different from said second delivery parameters and thereby cause different biomechanical effects on the tissue to which they are applied.

Mehra teaches cardiac fat pad stimulation using multiple electrodes, at multiple locations in the AV fat pad area with varying delivery parameters that are accepted to cause different biomechanical effects on the tissue to which the stimulation is applied, for the purpose of distinguishing between arrhythmias. The versatile electrode types, quantity, location and delivery parameters teach:

- generation of at least two different stimuli,

- wherein a first one of said devices/ electrodes delivers a first non-excitatory stimulus to a first portion of the heart, using first delivery parameters, and

- wherein a second one of said devices/ electrodes delivers a second non-excitatory stimulus to a second portion of the heart using second delivery parameters,

- wherein said first delivery parameters are different from said second delivery parameters and thereby cause different biomechanical effects on the tissue to which they are applied.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used:

- generation of at least two different stimuli,

- wherein a first one of said devices/ electrodes delivers a first non-excitatory stimulus to a first portion of the heart, using first delivery parameters, and

- wherein a second one of said devices/ electrodes delivers a second non-excitatory stimulus to a

second portion of the heart using second delivery parameters,

- wherein said first delivery parameters are different from said second delivery parameters and thereby cause different biomechanical effects on the tissue to which they are applied

in the Hill system in order to provide electrode configurations, electrode placement, electrode delivery parameter proven to have the desired impact on the AV nodal fat pad (abstract; column 2, lines 36-45; column 3, lines 45-50; column 7, line 65 – column 8, line 7; column 9, lines 43-55).

Specification

10. The amendment filed 5/4/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claim 1 the limitation of "biomechanical", which refers to biomechanical effects, and in claim 35 the limitation of "consecutive", which refers to 100 out of 5000 consecutive heartbeats.

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FRANCES OROPEZA whose telephone number is (571) 272-4953. The examiner can normally be reached on Monday and Tuesday from 9AM to 7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno, can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/FRANCES OROPEZA/
Examiner, Art Unit 3766
May 9, 2011

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766